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SUPERIOR COURT OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DEPARTMENT 304

LABORATORY CORPORATION OF AMERICA HOLDINGS and MYRIAD GENETICS, INC., Petitioners and Plaintiffs, v. STATE OF CALIFORNIA DEPARTMENT OF PUBLIC HEALTH; DR. TOMÁS ARAGÓN, in his official capacity as Director of the California Department of Public Health, Respondents and Defendants.	Case No. CPF-22-517872 ORDER GRANTING PETITIONERS' PETITIONS FOR WRIT OF MANDATE
BILLIONTOONE, INC., Petitioner/Plaintiff, v. CALIFORNIA DEPARTMENT OF PUBLIC HEALTH, and DOES 1 through 50; Respondents/Defendants.	Case No. CPF-22-517871

The petitions for writ of mandate and complaints for declaratory and injunctive relief filed by Petitioners Laboratory Corporation of America Holdings ("Labcorp") and Myriad Genetics, Inc. ("Myriad") and BillionToOne, Inc. ("BillionToOne") came on for hearing on March 21, 2023. Having considered the papers and pleadings on file in the action, and the arguments of counsel presented at the hearing, the Court hereby grants the petitions.

FACTUAL BACKGROUND[1]

These actions concern the validity of regulations adopted in 2022 by Respondent California Department of Public Health ("CDPH" or the "Department") under the Hereditary Disorders Act, Health & Safety Code § 124975 *et seq.*[2] By mandate of that Act, CDPH operates a statewide program for prenatal testing of genetic disorders and birth defects, the California Prenatal Screening Program ("PNS Program"). (Olney Decl. ¶ 3.) Under the PNS Program, a pregnant person in California may, upon electing to participate, obtain screening for potential indicators of certain fetal birth defects by submitting a blood sample to a Department-approved prenatal birth defects screening laboratory. (*Id.*) The screenings do not definitively determine the presence of a genetic condition or birth defect; rather, individuals with a fetus found to have a heightened chance of one of those birth defects are offered genetic counseling and diagnostic testing without additional fees through CDPH-approved prenatal diagnosis centers. (*Id.*) Diagnostic testing is typically conducted by amniocentesis or chorionic villus sampling (CVS),[3] under which genetic abnormalities can be more accurately identified than through screening tests. (*Id.*)

Those who choose to participate in the PNS Program currently may obtain two prenatal screening tests: (1) screening for three "trisomies,"[4] trisomies 21 (Down syndrome), 18 (Edwards syndrome), and

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[1] This statement of facts is based on the verified petitions for writ of mandate filed by Petitioners, the declarations filed by the parties in connection with the briefing on the petitions, and certain materials that are proper subjects of judicial notice. The joint petition filed by Petitioners Labcorp and Myriad is cited as "Labcorp Pet."

[2] The Hereditary Disorders Act is found at Health & Safety Code §§ 124975-124966, 125050, 125055, 125060, and 125065. (Health & Safety Code § 27(b).) Except as otherwise indicated, all further statutory citations in this order are to the Health & Safety Code.

[3] Amniocentesis is a surgical procedure for obtaining a sample of amniotic fluid from the amniotic sac in the uterus of a pregnant individual by inserting a hollow needle through the abdominal wall. CVS utilizes a needle to remove cells from the chorionic villus, part of the placenta, which are then biopsied. (Wauters Decl. ¶ 8.) Each of these invasive procedures carries a risk of miscarriage. (Devore Decl. ¶ 14.)

[4] Trisomies are genetic abnormalities involving three copies of a chromosome rather than a chromosomal

13 (Patau syndrome); and (2) screening for neural tube defects such as spina bifida, using maternal serum alpha-fetoprotein (MSAFP or AFP) screening. (*Id.* ¶ 5; see also Wauters Decl. ¶ 25 & Ex. J.) The PNS Program does not offer prenatal screening for other conditions such as fetal sex chromosome aneuploidies,[5] recessive single-gene disorders (cystic fibrosis, sickle cell disease, spinal muscular atrophy, and thalassemias),[6] fetal antigens,[7] or velo-cardio-facial (VCF) syndrome. (*Id.*) However, such conditions may be the subject of prenatal or postnatal diagnostic tests offered under other Department-run programs. (Olney Decl. ¶ 1 [Genetic Disease Screening Program includes the PNS Program, the California Newborn Screening Program, and the California Birth Defects Monitoring Program].)

Since its inception in 1986, the PNS Program has utilized a number of different screening methods. (*Id.* ¶ 8.) Until the regulations that are the focus of this action were adopted effective September 19, 2022, the Program utilized a biochemical method for trisomy screening, which screened only for two of the three "common" trisomies (21 and 18). (*Id.* ¶ 8.) For over a decade prior to that time, however, another screening method, cell-free fetal DNA ("cfDNA"), was available to detect genetic disorders, including trisomies 21, 18, 13, and sex chromosome aneuploidies ("SCAs"). (Labcorp Pet. ¶¶ 1, 20-21.) CfDNA is a noninvasive method for detecting certain genetic disorders that involves sampling DNA from fetal cells released by the placenta into the pregnant person's blood during pregnancy. (Wauters Decl. ¶ 9.) It is a far more sensitive and accurate method of prenatal screening than traditional biochemical methods. (Devore Decl. ¶ 15.)

Since between 2010 and 2012, private commercial laboratories like Petitioners Labcorp and Myriad have been offering cfDNA screening for trisomies 21, 18, and 13 as a primary screen. (Labcorp

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pair.

[5] An aneuploidy is a term that refers to an abnormal number of chromosomes. Trisomies are some of the most common aneuploidies. (Devore Decl. ¶ 7.) Sex chromosome aneuploidies (SCAs) refer to genetic abnormalities in the form of an extra or missing chromosome in the sex chromosomes; persons with SCAs can present with a wide variety of physical, cognitive, and functional impairments. (*Id.* ¶ 8.)

[6] Single-gene disorders are caused by DNA mutations in one particular gene. A recessive disorder is a single gene disorder that only occurs if both copies of the gene, one from each parent, carry the mutation. (Devore Decl. ¶ 9.)

[7] Maternal alloimmunization occurs when a woman makes red blood cell antibodies as a result of foreign blood mixing; these antibodies can cross the placenta and attack the fetus, a disease called hemolytic disease of the fetus and newborn (HDFN). A number of different red blood cell fetal antigens are associated with severe HDFN, and identifying their presence can streamline patient management for the majority of alloimmunized patients. (Devore Decl. ¶ 10.)

Pet. ¶ 21.) The PNS Program began utilizing cfDNA screening in 2013, but only as a follow-up diagnostic service for patients who initially screened as high-risk for fetal chromosomal abnormalities. (*Id.* & Ex. A at 1.) Thus, between 2013 and 2022, physicians and pregnant individuals had the choice to obtain primary cfDNA screening through private laboratories and to obtain follow up cfDNA screening either through the PNS Program or from a private laboratory outside of the Program. (*Id.* ¶ 21.)

The Petitioners in these related cases are among the private laboratories that first offered such cfDNA prenatal screening. Labcorp's MaterniT® 21 Test, first offered to Californians in 2011, was the first commercially available noninvasive prenatal screening test. (Wauters Decl. ¶ 13.) It is a cfDNA screen for chromosomal abnormalities, including not only the three common trisomies, but also trisomy 16 and trisomy 22, both of which may result in miscarriage. (*Id.*) Significantly, the test also screens for SCAs at the same time as the trisomy screening, and uses the same specimen to do so, which avoids patients needing another blood draw. (*Id.* ¶ 14.) Most of the California patients Labcorp served in 2021 (approximately 70%) who sought cfDNA screening for trisomies also had SCA screening performed. (*Id.*) Labcorp charges one price for this entire panel of screening (i.e., for trisomies and SCAs). (*Id.*) Labcorp's cfDNA screening is covered under Medi-Cal, whose members cannot be balance billed. (*Id.*) The majority of Labcorp's commercially insured patients are financially responsible for less than $100 when they obtain cfDNA screening. (*Id.*) Labcorp's MaterniT® 21 Test can be performed on pregnant individuals carrying triplets (or more fetuses), whereas other laboratories' cfDNA screening can only be conducted on persons carrying a single fetus or twins. (*Id.* ¶ 15.) It also has an option that allows patients to conduct follow-up screening (should it become necessary) using the same specimen, therefore avoiding a separate blood draw. (*Id.* ¶ 16.) These and other features are reasons why some patients and their physicians would prefer to have cfDNA screening performed by Labcorp, as opposed to another laboratory (including laboratories that contracted with CDPH for the PNS Program). (*Id.* ¶¶ 15-19.)

Similarly, Petitioner Myriad offers its PREQUEL® prenatal screening for chromosomal abnormalities including the three common trisomies, plus optional screening panels for sex chromosome analysis, microdeletions, and expanded aneuploid analysis. (Gonzales Decl. ¶¶ 3-4.) In July 2020, Myriad introduced its proprietary PREQUEL® prenatal screening with AMPLIFY™ technology, an

amplification technology that increases the fetal fraction of a sample such that more accurate detection of fetal chromosomal abnormalities is possible relative to conventional prenatal screening technologies. (*Id.* ¶ 5.)[8] This technology is particularly useful for pregnant individuals with a high body mass index (BMI), whose fetal fractions tend to be lower, making it challenging to identify fetal chromosomal abnormalities with sufficient confidence. (*Id.* ¶ 6.) This prenatal screen benefits a substantial number of pregnant persons who are overweight or obese. (*Id.* ¶¶ 8-11.)

Petitioner BillionToOne is a licensed clinical laboratory founded in 2016 that similarly provides non-invasive prenatal tests, including cfDNA tests, to pregnant individuals throughout the country, including California. (Atay Decl. ¶¶ 3-4.) Its primary product currently is the UNITY Screen™, a product that includes a panel of prenatal screenings for a variety of genetic conditions. (*Id.* ¶ 6.) The UNITY Screen™ tests for multiple chromosomal aneuploidies, including the three common trisomies, SCAs, multiple recessive single-gene disorders, and fetal antigens. (*Id.*) Since 2020, BillionToOne has provided over 23,000 prenatal tests to California residents, including for trisomies 21, 18 and 13. (*Id.* ¶ 8.)

Beginning in 2019, the Department began considering the possibility of adopting cfDNA screening for the common trisomies as a first-tier screen under the PNS Program. (Olney Decl. ¶ 9.) By 2020, the American College of Medical Genetics and Genomics and the American College of Obstetricians and Gynecologists had both identified cfDNA screening as the most accurate and reliable screening test for the common trisomies. (*Id.* ¶ 10; Devore Decl. ¶ 16.) From 2019 through 2021, the Department conducted consultations with "stakeholders," including medical specialists, laboratory and social scientists, as well as industry, advocacy and government representatives, regarding adoption of cfDNA screening. (*Id.* ¶¶ 9-14.) It did not, however, directly consult with the public or with communities and groups particularly affected by programs on hereditary disorders, such as organizations or support groups representing individuals with such disorders.

During 2021, the Department sent letters and requests for information to private commercial

[8] Fetal fraction describes the proportion of cfDNA molecules analyzed in non-invasive prenatal screening that originate from the fetal tissue rather than maternal tissue. A higher fetal fraction lends itself to more accurate results. (Gonzales Decl. ¶ 5.)

laboratories to elicit interest in serving as a state-contracted laboratory to provide cfDNA screening for trisomies 21, 18, and 13 for the PNS Program and its participants. (Labcorp Pet. ¶ 23.) It subsequently contracted with four laboratories to provide screening under the revised PNS Program: Natera, Quest Diagnostics, PerkinElmer, and the Southern California Permanente Medical Group (Kaiser South). (Olney Decl. ¶ 34.) Two of the Petitioners—Labcorp and Myriad—submitted applications but declined to participate in the PNS Program; BillionToOne did not submit a timely application. (*Id.* ¶¶ 34-36.)

On July 18, 2022, CDPH filed an emergency regulation to offer cfDNA testing for trisomies 21, 18, and 13 to pregnant California residents exclusively through the PNS Program. (Labcorp Pet. ¶ 24.) The Department provided no notice to the public, held no public hearings, did not seek input from communities or groups particularly affected by programs on hereditary disorders, such as organizations or support groups representing individuals with such disorders, and made no findings. (*Id.*) The July 2022 amendment to section 6253(e) of the regulations read as follows: "Only Department approved prenatal screening laboratories shall offer or provide prenatal screening for birth defects that are included in the Department's Prenatal Screening Program to California residents." (*Id.* ¶ 25.) According to the Department, this amendment gave the PNS Program, effective September 19, 2022, "exclusivity in California to screen for trisomies 21, 18, and 13, as well as maternal serum AFP for neural tube defects. No other labs operating in California may screen for trisomies 21, 18, and 13 using cfDNA methodologies." (*Id.* at Ex. E.) CDPH subsequently amended this regulation in September 2022—again without first providing notice to the public—such that it now reads as follows:

> Only Department approved prenatal birth defects screening laboratories shall offer or provide prenatal screening for fetal autosomal trisomies or prenatal screening for neural tube defects that are included in the Department's Prenatal Screening Program to California residents.

(*Id.* ¶ 27; 17 Cal. Code Regs. § 6523(e).) This regulation (referred to in this order as the Exclusivity Regulation) is the focus of this action.

On September 19, 2022, the regulations became effective. (*Id.* ¶ 26; Kauffman Decl. Ex. B-1.) On September 15, 2022, CDPH circulated a notice of public hearing to be held on October 26, 2022—more than one month ***after*** the regulations had already become effective, and after these lawsuits were filed. (*Id.* at Ex. M; Kauffman Decl. Ex. C-1 [Notice of Public Hearing mailed Sept. 15, 2022; "These

regulations are now in effect"].) Notably, the notice made no reference to the exclusivity provision of the new regulations. Over 100 people attended the public hearing, and over 20 attendees spoke. (See Kauffman Decl. ¶ 6 & Exs. C-2, C-3.) Those presenting comments included physicians, genetic counselors, and representatives of the American College of Obstetricians and Gynecologists, the California Medical Association, the California Clinical Laboratory Association, and the Society for Maternal Fetal Medicine. (*Id.*) Every one of the attendees expressed concerns about the process by which the regulations were adopted and/or their contents, including multiple comments that the PNS Program's limitation of prenatal screening to only the common trisomies and neural tube defects improperly excluded screening for SCAs and other more common conditions and did not meet the standard of care.

PROCEDURAL BACKGROUND

On September 16, 2022, Labcorp and Myriad filed a joint Verified Petition for Writ of Mandate and Complaint for Declaratory and Injunctive Relief against Defendant and Respondent CDPH. Respondent and Defendant Dr. Tomás Aragón is CDPH's Director. (Labcorp Pet. ¶ 6.) The same day, a similar Verified Petition for Writ of Mandate and Complaint for Declaratory and Injunctive Relief was filed in the companion case, *BillionToOne, Inc. v. California Department of Public Health, et al.*, San Francisco Superior Court Case Number CPF-22-517871 (the "*BillionToOne* action").

The Labcorp Petitioners set forth seven causes of action: (1) violation of Hereditary Disorders Act; violation of scope of authority; (2) violation of Hereditary Disorders Act; violation of rulemaking requirements; (3) violation of California's Administrative Procedure Act; (4) agency action that is arbitrary, capricious, without evidentiary support and/or contrary to California law; (5) writ of mandate; (6) declaratory relief; and (7) injunctive relief. (Labcorp Pet. ¶¶ 45-80.) Petitioners sought declaratory and injunctive relief to nullify the Exclusivity Regulation, as well as a writ of mandate requiring CDPH to lawfully execute the PNS Program. (*Id.*, Prayer for Relief.) BillionToOne set forth similar causes of action, plus additional claims for violation of the constitutional right to privacy under Article I, section 1 of the California Constitution and of the statutory right to privacy with respect to personal reproductive decisions guaranteed by § 123462. (BillionToOne Am. Pet. ¶¶ 136-140, 141-145.)

On October 31, 2022, after extensive briefing and a hearing, the Court (Hon. Richard B. Ulmer, Judge) issued an order granting Petitioners' motion for a preliminary injunction against the Department's implementation and enforcement of the Exclusivity Regulation.[9] The Court found that the Labcorp Petitioners had shown a likelihood of prevailing on the merits at trial on, "at a minimum," their second cause of action for "violation of rulemaking requirements." (Oct. 31, 2022 Order, 2.) In this cause of action, which the Court referred to as a "gating claim," Petitioners pled that the Department had failed to consult the public and experts before adopting the amended regulations and instead adopting them as unauthorized "emergency" regulations. (*Id.* at 2-3.) The Court pointed out that the Department had effectively conceded that it did not comply with the provisions of the Hereditary Disorders Act expressly requiring it to consult with the public before adopting any regulations and standards. The Court rejected the Department's arguments that the amended regulations were properly adopted as emergency regulations, observing that "cfDNA screening had been conducted for over a decade in California and the opposition cites no crisis." (*Id.* at 3.) It went on to reject the Department's argument that *all* of its regulations are properly considered "emergency" regulations, such that it need never consult or notify the public before adopting regulations. (*Id.* at 3-4.) The Court also found that the relative interim harm to the parties weighed in Petitioners' favor, reasoning that barring Petitioners from the California market for cfDNA screening would cause harm in the form of lost revenue, goodwill and innovative momentum, whereas "defendants fail to show significant harm from maintaining the pre-September 2022 status quo for the relatively short time it should take to adjudicate" the underlying case. (*Id.* at 4.)

On November 2, 2022, the Court issued its preliminary injunction, which enjoined the Department from "enforcing and/or implementing amended California Code of Regulations, title 17, section 5623(e) and from taking any action to prohibit or restrain otherwise licensed laboratories from providing cfDNA prenatal laboratory screening services, and from taking any steps to prohibit or restrain any California patients or healthcare providers from obtaining cfDNA screening services from any non-CDPH-contracted, otherwise licensed, laboratories." (Nov. 2, 2022 Preliminary Injunction, 2.) The Court stated that the order "does not preclude the PNS Program from offering, providing information about and

[9] The order was issued solely in the *Labcorp* action (No. 22-517872). In view of that order, the Court deemed BillionToOne's similar motion moot.

making cfDNA and other prenatal screening available to prospective participants who may choose to obtain screening through the PNS Program." (*Id.*)[10]

The parties were unable to agree on the amount of the bond or undertaking to be filed by Petitioners as a condition of the preliminary injunction. Petitioners proposed that the Court set the bond at $10,000; Defendants, in contrast, sought a bond in excess of $101 million, which they contended represented "an estimate of the reasonably foreseeable additional costs resulting from the injunction." The Court ultimately ordered Petitioners to file an undertaking in the amount of $50,000 pending trial of the action.

On November 7, 2022, the Court issued an order designating the action complex and transferring it to the undersigned judicial officer. On the same date, Defendants filed an objection to the amount of the undertaking or bond on the ground that it was not adequate to cover the reasonably foreseeable damages they estimated may be caused by the preliminary injunction. Defendants subsequently filed an expanded notice of objection, supported by two declarations, in which they sought a bond in the increased amount of $4,010,019, comprised of $3,953,187 in estimated financial harm to the PNS Program for the nine-month period following the issuance of the preliminary injunction, plus $56,922 in legal fees in connection with the projected appeal. Petitioners opposed the objection, and maintained that the Court should leave in place the current bond in the amount of $50,000.

By order filed December 7, 2022, the Court overruled the Department's objection to the amount of the undertaking. The Department's prior request for a $101 million bond was based on the assumption that the preliminary injunction would result in an approximately 25 percent reduction in screening cases within the PNS Program, thereby reducing its projected annual case load by an equivalent percentage, and would therefore result in decreased cfDNA fee revenues, offset to some degree by decreased program expenditures. (Dec. 7, 2022 Order, 5.) The Department asserted it would require a fee increase of approximately $30 per cfDNA specimen to make up for this deficit and comply with the Legislature's mandate that the Program be fully supported by program participation fees, but assumed that it could not obtain authorization for such an increase for about nine months. (*Id.* at 5-6.) Notably, however, the

[10] The Department appealed from the order and preliminary injunction. (No. A166479 (filed Dec. 5, 2022).)

Department made no effort to explain the enormous discrepancy between the $101 million amount it had previously claimed to be "an estimate of the reasonably foreseeable additional costs resulting from the injunction" and the $4 million it sought in its objection, other than to assert in conclusory fashion that since it conveyed its initial demand for a $101 million bond, it "had a greater opportunity to consider the basis for an estimate of those damages." (Dec. 7, 2022 Order, 6.)

The Court found that Defendants offered no factual basis for the key assumption underlying their calculations, i.e., that the preliminary injunction would result in a 25% reduction in their projected case load. (*Id.*) It also pointed out that the Department "[did] not address the comparative prices of the screening services it offers through contracted laboratories and those offered by Plaintiffs and other noncontracted private laboratories, nor [did] it explain why a given healthcare provider would order tests outside the PNS Program," thereby undermining the reliability of the Department's showing. (*Id.* at 7.) The Court also observed that the State had only recently begun offering the cfDNA screening services for trisomies, which further reduced the reliability of its projections, and concluded that "[t]he Department's largely unexplained 'estimate' of projected future lost revenues from a newly established program is not a sufficiently reliable or admissible basis for setting a bond amount." (*Id.* at 7-8.) Finally, the Court indicated that because it intended to hold a hearing on the merits in substantially less than the nine-month period of time the Department had used to calculate its estimate of costs, any damages to the Department from the preliminary injunction would be limited. (*Id.* at 8.)

Petitioners now move for judgment on their writ petitions, and ask the Court to issue a writ of mandate directing CDPH to not enforce the Exclusivity Regulation and declare it to be unlawful and void. (Joint Brief, 26.) Petitioners challenge the Exclusivity Regulation on several grounds, including (1) that it violates the Hereditary Disorder Act's mandate that the PNS Program be "wholly voluntary"; (2) that it exceeds CDPH's statutory authority and conflicts with the Act's purpose; (3) that CDPH failed to comply with the requisite rulemaking requirements; and (4) that it violates pregnant patients' privacy rights.[11] The Department opposes the motion.[12] The Court agrees with Petitioners' position on the

[11] The last ground is asserted only by Petitioner BillionToOne.

[12] CDPH's request for judicial notice is granted. CDPH's objections to Plaintiffs' evidence are overruled as untimely. (See Cal. Rules of Court, rule 3.1354.) In any event, the parties' evidentiary disputes are largely immaterial to the issues before the Court.

second and third grounds, and therefore need not reach the remaining issues.

LEGAL STANDARD

Petitioners' claim that the Exclusivity Regulation exceeds the Department's delegated power under the Hereditary Disorders Act is subject to a two-part test:

> In reviewing the legality of a regulation adopted pursuant to a delegation of legislative power, the judicial function is limited to determining whether the regulation (1) is within the scope of the authority conferred and (2) is reasonably necessary to effectuate the purpose of the statute. These issues do not present a matter for the independent judgment of [a court]; rather, both come to this court freighted with [a] strong presumption of regularity.... Our inquiry necessarily is confined to the question whether the classification is arbitrary, capricious or without reasonable or rational basis. Of all administrative decisions, quasi-legislative acts receive the most deferential level of judicial scrutiny. Civil statutes enacted to protect the public are generally broadly or liberally applied in favor of that protective purpose.

(*Western Growers Assn. v. Occupational Safety & Health Standards Bd.* (2021) 73 Cal.App.5th 916, 932 (cleaned up).) "At the same time, when an implementing regulation is challenged on the ground that it is in conflict with the statute or does not lay within the lawmaking authority delegated by the Legislature, the issue of statutory construction is a question of law on which a court exercises independent judgment." (*Western States Petroleum Assn. v. Bd. of Equalization* (2013) 57 Cal.4th 401, 415 (cleaned up).) "[W]e conduct independent review of whether defendants have exceeded the scope of authority delegated by the Legislature to them or the meaning of a statute. Deference is not accorded to an administrative action which is incorrect in light of unambiguous statutory language or which is clearly erroneous or unauthorized. Nor can we, in construing a remedial statute liberally, apply it in a manner not reasonably supported by its statutory language." (*Western Growers Assn.*, 73 Cal.App.5th at 932 (cleaned up).) Moreover, a court "does not . . . defer to an agency's view when deciding whether a regulation lies within the scope of the authority delegated by the Legislature. The court, not the agency, has final responsibility for the interpretation of the law under which the regulation was issued." (*Yamaha Corp. v. State Bd. of Equalization* (1998) 19 Cal.4th 1, 6 fn. 4; see also *In re McGhee* (2019) 39 Cal.App.5th 902, 908-909.)

Petitioners' claim that the Department violated provisions of the Hereditary Disorders Act, including a statute that directs the Department to consult with the public before adopting regulations, raises an issue of statutory interpretation. "As in any case involving statutory interpretation, our

fundamental task here is to determine the Legislature's intent so as to effectuate the law's purpose. We begin by examining the statute's words, giving them a plain and commonsense meaning." (*People v. Lewis* (2021) 11 Cal.5th 952, 961 (cleaned up).) "The plain meaning controls if there is no ambiguity in the statutory language." (*Poole v. Orange County Fire Authority* (2015) 61 Cal.4th 1378, 1385 (cleaned up).) "The Legislature does not engage in idle acts, and no part of its enactments should be rendered surplusage if a construction is available that avoids doing so." (*Kaanaana v. Barrett Business Services, Inc.* (2021) 11 Cal.5th 158, 172 (cleaned up).) "In interpreting a statutory provision, our task is to select the construction that comports most closely with the Legislature's apparent intent, with a view to promoting rather than defeating the statute's general purpose, and to avoid a construction that would lead to unreasonable, impractical, or arbitrary results." (*Poole*, 61 Cal.4th at 1385 (cleaned up).)

DISCUSSION

I. THE EXCLUSIVITY REGULATION EXCEEDS THE DEPARTMENT'S DELEGATED AUTHORITY UNDER THE HEREDITARY DISORDERS ACT.

The crux of Petitioners' claims turns on whether the Exclusivity Regulation is within the scope of the authority delegated to the Department by the Legislature. The Court concludes that the Exclusivity Regulation is beyond the scope of the Department's authority because the Legislature neither explicitly nor impliedly delegated authority to the Department to prohibit licensed clinical laboratories from providing prenatal screening. Such a prohibition would undermine rather than further the purpose of that Act, which is to expand rather than restrict the availability of prenatal screening for birth defects for pregnant persons in the State of California; would detract from the Legislature's directive that participation in the PNS Program must be "wholly voluntary"; and would conflict with the well-established public policy favoring free competition. The Department's justifications for adopting the Exclusivity Regulation are based almost entirely on economics, not public health, and are unpersuasive.

A. The Legislature Did Not Authorize The Department To Prohibit Licensed Clinical Laboratories From Offering Prenatal Screening Tests.

In enacting the Hereditary Disorders Act, the Legislature made extensive supporting findings. (§ 124975.) It found that "[h]ereditary disorders, such as sickle cell anemia, cystic fibrosis, and hemophilia,

are often costly, tragic, and sometimes deadly burdens to the health and well-being of the citizens of this state." (§ 124975(a).) Further, "[d]etection through screening of hereditary disorders can lead to the alleviation of the disability of some hereditary disorders and contribute to the further understanding and accumulation of medical knowledge about hereditary disorders that may lead to their eventual alleviation or cure." (§ 124975(c).) The Legislature emphasized the importance of adapting legislation and policy over time in light of "rapidly expanding medical knowledge, underscoring the need for flexible approaches to coping with genetic problems." (§ 124975(g).) Thus, "State policy regarding hereditary disorders should be made with full public knowledge, in light of expert opinion and should be constantly reviewed to consider changing medical knowledge and ensure full public protection." (§ 124975(h).) The Legislature also emphasized that "[p]articipation of persons in hereditary disorders in the State of California should be wholly voluntary,"[13] and that "[a]ll information obtained from persons involved in hereditary disorders programs in the state should be held strictly confidential." (§ 124975(j).) The Legislature directed "all programs offering screening programs for heredity disorders [to] comply with the principles established in the Hereditary Disorders Act," and found it "necessary to establish a uniform statewide policy for the screening for heredity disorder in the State of California." (§ 124975(k).)

The Hereditary Disorders Act provides that the Department "shall administer a statewide program for the prenatal testing for genetic disorders and birth defects, including, but not limited to, ultrasound, amniocentesis, chorionic villus sampling, and blood testing for genetic disorders and birth defects." (§ 125050.) The Department is mandated to undertake a variety of tasks in connection with the PNS Program, including establishing criteria for eligibility for the prenatal testing program; developing an education program designed to educate physicians, surgeons, and the public concerning the uses of prenatal testing and the availability of the program; ensuring that genetic counseling is given in conjunction with prenatal testing; designating sufficient prenatal diagnosis centers; and administering a program of subsidy grants for approved nonprofit prenatal diagnosis centers. (§ 125055(a)-(e).) The Department "shall expand prenatal screening to include all tests that meet or exceed the current standard

[13] The Legislature carved out a single exception to this voluntariness requirement for "initial screening for phenylketonuria (PKU) and other genetic disorders treatable through the California newborn screening program." (§ 124975(j).)

of care as recommended by nationally recognized medical or genetic organizations." (§ 125055(g)(1).)

The Hereditary Disorders Act confers authority on the Department to "establish any regulations and standards for hereditary disorders programs as the director deems necessary to promote and protect the public health and safety." (§ 124980; see also § 125055(f) [similar provision addressing prenatal diagnostic testing].) However, the Legislature did not grant the Department unlimited discretion to develop such regulations and standards. Rather, it directed that regulations adopted by the Department "shall implement the principles established in this section." (§ 124980.) That provision is followed by thirteen detailed subparagraphs articulating the "principles" that the Department is to follow in those regulations, covering a broad range of subject matters including the accuracy of clinical testing procedures, a requirement of parental consent to test minors, the availability of pretest and post-test counseling services for hereditary disorders, informed consent regarding the risks involved in participation in the programs, and the availability and confidentiality of testing results. (§ 124980(b)-(m).) None of those provisions so much as hints that the Department may render the PNS Program the sole option available to pregnant persons or bar non-participating health care providers from offering prenatal screening tests. To the contrary, as discussed below, one of those provisions specifies that with one exception, "No testing . . . shall require mandatory participation." (§ 124980(f).)

Thus, as the Department readily conceded at the hearing, nothing in the express language of the Act, or in its legislative history, suggests that the Legislature intended to authorize the Department to bar non-contracted but otherwise qualified licensed clinical laboratories from offering prenatal screening *outside* the Program, or for the PNS Program to occupy the field of prenatal screening. The conceded absence of such statutory language undermines the Department's position. "The authority of an administrative agency to adopt regulations is limited by the enabling legislation. An administrative regulation must be within the scope of authority conferred and in accordance with standards prescribed by other provisions of law." (*Bearden v. U.S. Borax, Inc.* (2006) 138 Cal.App.4th 429, 435-436 (cleaned up) [holding that the Industrial Welfare Commission exceeded its authority in creating a meal period exemption for employees covered by qualifying collective bargaining agreements not codified in the Labor Code].) "It is not the role of the courts to add statutory provisions the Legislature could have

provided, but did not." (*Artus v. Gramercy Towers Condominium Assn.* (2018) 19 Cal.App.5th 923, 945.) "Even apart from these statutory limits, it is well established that the rulemaking power of an administrative agency does not permit the agency to exceed the scope of authority conferred on the agency by the Legislature." (*Bearden*, 138 Cal.App.4th at 436; see also, e.g., *Fipke v. California Horse Racing Board* (2020) 55 Cal.App.5th 505, 516 ["an administrative agency may not adopt a regulation that exceeds the scope of, or is inconsistent with, the enabling statute" (cleaned up)]; Gov. Code § 11342.2.) "Administrative regulations that alter or amend the statute or enlarge or impair its scope are void and courts not only may, but it is their obligation to strike down such regulations." (*Pulaski v. California Occupational Safety and Health Standards Board* (1999) 75 Cal.App.4th 1315, 1341 (cleaned up) [regulation that was inconsistent with statute was "jurisdictionally infirm"].)

In apparent recognition that its position finds no support in the language of the Act, the Department asserts that the Legislature has "acquiesced" to the exclusivity requirement. Thus, the Department contends that "the Legislature is aware of the Department's requirement that laboratories be approved by entering into a contract with the Department to provide screening tests included in the PNS Program and has repeatedly amended relevant provisions of the Act, but has never required in over 35 years that the requirement be withdrawn." (Opposition, 7.)[14] The Court is unpersuaded.

In the first place, the Legislature's silence or failure to correct an agency's interpretation of a statutory scheme cannot substitute for an affirmative delegation of authority. Moreover, "[a]s a principle of statutory construction, legislative inaction is a slim reed upon which to lean." (*Grosset v. Wenaas* (2008) 42 Cal.4th 1100, 1177 (cleaned up).) The Department stretches to apply the doctrine, not to the Legislature's presumed awareness of a consistent body of judicial precedents, but rather to a single regulation that it fails to show the Legislature as a whole had substantial reason to be aware of. (Cf. *Mendoza v. Fonseca McElroy Grinding Co., Inc.* (2021) 11 Cal.5th 1118, 1141 ["An administrative interpretation that is clearly erroneous, even if long-standing and consistent, is entitled to no

[14] The Department's showing established that prior versions of the regulation had required that prenatal screening laboratories be "approved" by the Department and submit bids acceptable to the Department to provide laboratory services, although they did not contain an explicit exclusivity requirement comparable to that in amended § 6523(e). (RJN, Ex. B (1986 regulations), former § 6523(a),(b); Ex. C (1997 regulations), former § 6523(a),(b).)

deference."].)[15] That the Department responded to inquiries and had meetings with individual legislators and their staff in which the exclusivity requirement was discussed (Olney Decl. ¶ 14), or mentioned it in a single hearing before a budget subcommittee (*id.* ¶¶ 21-22), is insufficient to warrant drawing any convincing inference from the Legislature's inaction.

The Department's related argument based on the failure of a recent proposed amendment to the Act that would have explicitly repealed the exclusivity requirement (*id.* ¶ 23; Opposition, 12-13; RJN, Exs. D-G) is, if anything, even less persuasive. "We can rarely determine from the failure of the Legislature to pass a particular bill what the intent of the Legislature is with respect to existing law." (*People v. Mendoza* (2000) 23 Cal.4th 896, 921 (cleaned up); see also *Martin v. Szeto* (2004) 32 Cal.4th 445, 451 ["We have repeatedly observed that the Legislature's failure to enact a proposed amendment to an existing statutory scheme offers only limited guidance, if any, concerning the Legislature's original intent."].)[16]

B. Barring Licensed Clinical Laboratories From Offering Prenatal Screening Tests Would Restrict Access To Prenatal Testing, Render The Program Mandatory Rather Than Voluntary, And Violate Public Policy Favoring Free Competition.

Thus, nothing in the express language of the Hereditary Disorders Act supports the Department's position that the Legislature delegated authority to it under that Act to prohibit otherwise qualified, licensed clinical laboratories from offering prenatal screening tests to pregnant persons who wish to obtain them. Nor is there any basis for concluding that the Legislature *impliedly*, rather than expressly, delegated such authority to the Department. For several reasons, the Department's argument that the Court should find such an implied delegation of authority is unpersuasive.

First, such forced exclusivity undermines rather than furthers the purpose of the Act. The Legislature found that "[d]etection through screening of hereditary disorders can lead to the alleviation of

[15] Dr. Olney's asserted "understanding" that the exclusivity requirement "was a subject of significant debate when the PNS Program was authorized under the Hereditary Disorders Act" in 1986 (Olney Decl. ¶ 18)—29 years before he assumed his current position in 2015—lacks personal knowledge and constitutes inadmissible hearsay. Petitioners' objection to that assertion is sustained.

[16] The limited legislative history of SB 771 that the Department supplied strongly suggests that the bill failed of passage for reasons having nothing to do with its merits. (See RJN, Ex. E at 7 ["The extremely shortened legislative process that this bill will receive does not give the public and stakeholders sufficient opportunity to be heard and evaluate the importance and utility of additional screening"]; Ex. F at 3 ["this bill will be heard in only one policy committee and one fiscal committee"].)

the disability of some hereditary disorders and contribute to the further understanding and accumulation of medical knowledge about hereditary disorders that may lead to their eventual alleviation or cure." (§ 124975(c).) But the Exclusivity Regulation *restricts*, rather than expands, the prenatal screening tests available to pregnant persons in California. Patients may obtain the limited screening tests available under the PNS Program only from the four laboratories that contracted with the Department. By the terms of the Exclusivity Regulation, licensed clinical laboratories such as Petitioners are prohibited from conducting any prenatal screening testing for the conditions included in the PNS Program—even if those tests are included in a single panel that also tests for other conditions that are outside the scope of the Program, such as fetal SCAs, recessive single-gene disorders, and fetal antigens. Patients who wish to obtain broader prenatal screening for those other conditions must obtain two separate tests, one through the PNS Program and one outside the Program. That requirement imposes additional burdens in terms of time, paperwork, and cost, and reduces the likelihood that pregnant patients will obtain the full screening results. (See Devore Decl. ¶¶ 19-25;[17] Rhee Decl. ¶¶ 7-11;[18] Wauters Decl. ¶ 28.) Moreover, the exclusivity requirement prevents patients with particular characteristics, such as individuals who are pregnant with triplets or who have a high BMI, from accessing Petitioners' specialized tests. (Wauters Decl. ¶¶ 15-17; Gonzales Decl. ¶ 10.)

Second, the Exclusivity Regulation also conflicts with the Act's directive that "[t]he participation by any individual in the prenatal testing program shall be wholly voluntary and shall not be a prerequisite to eligibility for, or receipt of, any other service or assistance from, or participation in, any other program." (§ 125060; see also *id.* § 124980(f) [with certain exceptions, "[n]o testing . . . shall require

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[17] One declarant, a physician who specializes in maternal and fetal medicine, underscores that the regulation will reduce the likelihood that patients will be screened for chromosomal aneuploidies generally (that is, SCAs, not just the common trisomies) because none of the PNS-contracted laboratories offers SCA testing as part of a package funded by the State of California. (Devore Decl. ¶ 20.) Yet SCAs are collectively more common than the trisomies, and individuals with SCAs can suffer from serious symptoms. (*Id.* ¶ 21.)

[18] As another declarant, a board-certified genetic counselor, explains, "because CDPH's changes have, at a minimum, doubled the number of cfDNA tests that a patient must order, patients who cannot or are not willing to pay for the costs associated with an additional test will forego the screening. And if I cannot provide genetic counseling to my patients for these additional abnormalities, I risk missed diagnosis and missed treatment opportunities that would have been discussed as part of my regular practice." (Rhee Decl. ¶ 9.) Further, "CDPH's regulation negatively affects patient access to medical care because patients can no longer select a cfDNA screening test that is best tailored to their individual needs." (*Id.* ¶ 10.)

mandatory participation."].) In light of the exclusivity requirement, any pregnant individual who wishes to obtain prenatal screening for the common trisomies and neural tube defects may obtain those tests only through the contracted laboratories, or literally must leave the State of California to seek such testing elsewhere. Indeed, the Department effectively concedes the point, asserting that "any person who does not wish to obtain screening through the PNS Program remains free to obtain it outside of California." (Opposition, 17.) Thus, participation in the PNS Program is not "voluntary." (See Rhee Decl. ¶ 11 ["CDPH's new regulation will force women to participate in PNS even though they may have otherwise preferred to opt out and obtain cfDNA screening elsewhere"].)[19]

Third, public policy embodied in the Cartwright Act, Bus. & Prof. Code § 16720 *et seq.*, California's antitrust law, favors free competition and disfavors monopolistic arrangements—whether they are entered into by private parties or, as here, created and condoned by the State itself. (See, e.g., *In re Cipro Cases I & II* (2015) 61 Cal.4th 116, 136 [the Cartwright Act "rests on the premise that the unrestrained interaction of competitive forces will yield the best allocation of our economic resources, the lowest prices, the highest quality and the greatest material progress, while at the same time providing an environment conducive to the preservation of our democratic political and social institutions. At its heart is a prohibition against agreements that prevent the growth of healthy, competitive markets for goods and services and the establishment of prices through market forces." (cleaned up)].) This public policy applies equally in the healthcare field. (See, e.g., *Ben-E-Lect v. Anthem Blue Cross Life & Health Ins. Co.* (2020) 51 Cal.App.4th 867, 872-874 [affirming judgment for third party insurance claim administrator against health insurance plan providers for illegal vertical boycott].) Had the Legislature intended to authorize the Department to depart from this fundamental public policy and effectively mandate a government-created monopoly over prenatal screening testing, "it would have said so. The Legislature does not, one might say, hide elephants in mouseholes." (*Hester v. Public Storage* (2020) 49 Cal.App.5th

[19] The Department contends that the statutory provision that participation shall be "voluntary" means merely that "pregnant individuals remain free to choose whether or not to participate in the Program." (Opposition, 16.) The Department's strained reading is unreasonable. Pregnant persons who wish to obtain the covered prenatal tests must obtain them through the PNS Program. That "choice" in truth is no choice at all, and is hardly "voluntary." (See *Arriaga v. County of Alameda* (1995) 9 Cal.4th 1055, 1064 ["As generally understood, the term 'voluntary' at minimum means an exercise of will, i.e., it implies freedom from any compulsion that could constrain one's choice." (cleaned up)].)

668, 676 (cleaned up).)[20]

C. The Department's Justifications for the Exclusivity Regulation Are Unpersuasive.

The Department's principal justifications for the Exclusivity Regulation relate to economics, not to public health. They are less than compelling, but even if they were fully supported by the record, they cannot establish that the Legislature delegated authority to the Department to adopt the Exclusivity Regulation.

The Department asserts that it has been able to enter into contracts with laboratories to conduct the screening tests at rates "below prevailing market rates," and that "[i]f laboratories were permitted to conduct these screenings outside of the PNS Program, there is a substantial risk that most if not all providers would decline to contract with the Department to provide Program screenings because of the potential availability of greater earnings from private payments that are not capped at the PNS Program rate, and because the anticipated economies of scale that provide an incentive to accept lower screening rates would be upset." (Olney Decl. ¶ 27.) In other words, the Department contends that absent the Exclusivity Regulation, laboratories will charge higher prices for prenatal testing, thus increasing the cost to the Department and the State of the PNS Program and threatening the viability of the entire Program.[21] However, as the Court found in overruling the Department's objection to the bond amount, its showing in that regard was speculative. But even if the Department's economic concerns were fully supported, they do not make a compelling case for exclusivity, since at most they suggest the need for a modest increase in fees to support the PNS Program. The Act states the Legislature's intent that "the genetic disease testing program carried out pursuant to this chapter be fully supported from fees collected for services provided by the program." (§ 124977(a).) "The department shall charge a fee to all payers for any tests

[20] Public utilities enjoy a monopolistic or quasi-monopolistic authority that derives directly from the exclusive franchise provided by the state. (*Pacific Bell Telephone Co. v. Southern California Edison Co.* (2012) 208 Cal.App.4th 1400, 1406.) With that unique exception, the Court is hard put to identify any other situation where the Legislature has conferred monopolistic authority on private entities—and none in which it has done so *sub silentio*, as the Department contends occurred here.

[21] The Department's showing asserted that the market rate billed by laboratories for cfDNA common trisomy screening previously had averaged approximately $695, and that prior to cfDNA common trisomy screening being adopted as a first-tier PNS Program screen, Medi-Cal paid $607 for cfDNA common trisomy screening and $1,500 for diagnostic counseling and testing. (Olney Decl. ¶ 29.) It is unclear from the record what percentage of the cost of the PNS Program is paid for by Medi-Cal and private insurers, rather than by the Department.

or activities performed pursuant to this chapter. The amount of the fee shall be established by regulation and periodically adjusted by the director in order to meet the costs of this chapter." (§ 124977(b)(1).) That is exactly what the Department has done in the past.[22]

In any event, the Department's economic concerns cannot establish that the Legislature impliedly delegated authority to it to adopt the Exclusivity Regulation. Nowhere did the Legislature direct the Department to grant clinical laboratories exclusive contractual authority to conduct screening tests, thereby freezing out potential competitors and restricting patients' access to tests, in order to fix prices at an artificially low level. In any event, the vast majority of Petitioners' services are covered by Medi-Cal and private health insurance. (Wauters Decl. ¶ 14; Atay Decl. ¶ 5.)[23]

II. THE DEPARTMENT FAILED TO COMPLY WITH ITS MANDATORY STATUTORY OBLIGATION TO CONSULT WITH THE PUBLIC AND GROUPS AFFECTED BY PROGRAMS ON HEREDITARY DISORDERS BEFORE ADOPTING THE EXCLUSIVITY REGULATION.

The Exclusivity Regulation is invalid for a second, independent reason: in adopting it, the Department violated the rulemaking provisions of the Hereditary Disorders Act, which expressly required it to consult with the public and affected groups ***before*** adopting any regulations. As noted above, the Act provides that the Department "shall establish any regulations and standards for hereditary disorders programs as the director deems necessary to promote and protect the public health and safety." (§ 124980.) However, the Legislature did not grant the Department unlimited discretion to develop such

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[22] Before the amended regulations were adopted effective September 19, 2022, the all-inclusive participation fee for the NPS Program was $221.60. (Kauffman Decl. Ex. B-1 [July 7, 2022 Memorandum from CDPH to Office of Administrative Law].) Section 6540 of the Department's regulations, entitled "Program Participation Fees," states that the current all-inclusive program participation fee for prenatal screening for neural tube defects shall be $85.00, while the program participation fee for prenatal screening for fetal autosomal trisomies shall be $232.00. (17 Cal. Code Regs. § 6540(a),(b).) In each case, the fee "shall be paid to the Department by the individual being tested or by any third party which is legally responsible for their care, including any health care service plan, managed health care plan, managed care plan, prepaid health plan or prepaid group practice health care service plan." (*Id.*)

[23] The Department's remaining justifications for the exclusivity requirement are equally unpersuasive. Although the Department points generally to the need to enforce and police performance standards (Olney Decl. ¶¶ 25-26), it is undisputed that Petitioners, among other qualified, licensed clinical laboratories, offered cfDNA prenatal screening testing for years before the Department adopted it as part of the PNS Program, yet there is no indication that the Department expressed any concern about the accuracy or quality of their tests or any other aspect of their operations. The argument is a makeweight.

regulations and standards. Rather, it mandated that regulations adopted by the Department "*shall* implement the principles established in this section." (*Id.* (emphasis added).) The very first of those principles reads,

> The public, especially communities and groups particularly affected by programs on hereditary disorders, should be consulted before any regulations and standards are adopted by the department.

(§ 124980(a); see also § 124975(h) ["State policy regarding hereditary disorders should be made with full public knowledge, in light of expert opinion and should be constantly reviewed to consider changing medical knowledge and ensure full public protection."].)[24] As discussed above, however, the Department did not provide public notice or hold a public hearing before adopting the disputed regulations. Nor did it consult with "groups particularly affected by programs on hereditary disorders," such as organizations or support groups representing individuals with such disorders (e.g., associations concerned either with disorders covered by the PNS Program, such as Down Syndrome or spina bifida, or with disorders outside the Program's scope, such as cystic fibrosis or sickle cell anemia).

The Department makes two arguments in an attempt to avoid the conclusion that it violated Section 124980. First, it argues that the language of Section 124980 is merely "hortatory," emphasizing that it utilizes the word "should" rather than "shall." (Opposition, 25.) The Department is correct that in general, the word "should" is construed to be permissive or advisory rather than mandatory. (See, e.g., *Lueras v. BAC Home Loans Servicing, LP* (2013) 221 Cal.App.4th 49, 74-75.) Here, however, in language that the Department ignores, the statutory directive that the public "should be consulted" before the Department adopts regulations follows the mandatory command that the regulations "***shall***" implement that principle, which logically implies that the Legislature intended that principle to be binding on the Department, not merely permissive. "Under well-settled principles of statutory construction, we ordinarily construe the word 'may' as permissive and the word 'shall' as mandatory, particularly when a single statute uses both terms." (*Tarrant Bell Property, LLC v. Superior Court* (2011) 51 Cal.4th 538, 542 (cleaned up).)[25]

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[24] The Legislature separately directed that "where appropriate, state and national experts in the medical, psychological, ethical, social, and economic effects or programs for the detection and management of hereditary disorders shall be consulted by the department." (§ 124980(b).)

[25] In *Creason v. Department of Health Services* (1998) 18 Cal.4th 623, the Court rejected a claim that the

Second, the Department relies heavily on two provisions of the Act which state that it may adopt emergency regulations without complying with otherwise applicable provisions of the Administrative Procedure Act. (§§ 124977(d)(1), 12055(g)(4)(B).) Thus, Section 124977(d)(1) states,

> The department may adopt emergency regulations to implement and make specific this chapter in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. For the purposes of the Administrative Procedure Act, the adoption of regulations shall be deemed an emergency and necessary for the immediate preservation of the public peace, health and safety, or general welfare. Notwithstanding Chapter 3.5 . . . , these emergency regulations shall not be subject to the review and approval of the Office of Administrative Law. Notwithstanding Sections 11346.1 and 11349.6 of the Government Code, the department shall submit these regulations directly to the Secretary of State for filing. The regulations shall become effective immediately upon filing with the Secretary of State. Regulations shall be subject to public hearing within 120 days of filing with the Secretary of State and shall comply with Sections 11346.8 and 11346.9 of the Government Code or shall be repealed.

(§ 124977(d)(1).)[26] Section 125055(g)(4)(B) in similar language authorizes the Department to adopt emergency regulations to implement and make specific the amendments to that statute made during the Legislature's 2005-06 Regular Session. (§ 125055(g)(4)(B).) That provision referred to Section 125055(g)(1), which required the Department to expand prenatal screening to include "all tests that meet or exceed the current standard of care as recommended by nationally recognized medical or genetic organizations, including, but not limited to, inhibin." The Department argues that, as later and more specific provisions, these statutes control over any arguably conflicting directive of Section 124980. (Opposition, 25.) As the Department acknowledges, however, those principles apply only to the extent that the two statutes cannot be reconciled. (*State Dept. of Public Health v. Superior Court* (2015) 60 Cal.4th 940, 955.) "A court must, where reasonably possible, harmonize statutes, reconcile seeming

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Department breached a mandatory duty to devise accurate testing and reporting standards for hypothyroidism, holding that "the Legislature left the selection of necessary and appropriate testing and reporting standards to the sound discretion of the Director, guided by certain 'principles' that the Director should consider in drafting those standards." (*Id.* at 632.) It concluded, as a result, that the Act does not impose "a mandatory duty on the Department to select or impose any particular testing or reporting standard or component, and that the Director's allegedly negligent exercise of discretion in selecting a particular standard will not support a cause of action under Government Code section 815.6." (*Id.* at 635.) That opinion did not address the distinct provision of Section 124980 involved here, which by its plain language does not confer any discretion on the Department—either it consults with the public before adopting regulations or it does not.

[26] Petitioners argue that § 124977 contains a "scrivener's error," in that the reference to "emergency regulations to implement and make specific this chapter" should read "to implement and make specific this *section*." While Petitioners are correct that the Department's broad reading of § 124977 would seem to render § 125055 surplusage, the Court need not reach that argument here.

inconsistencies in them, and construe them to give force and effect to all of their provisions." (*Id.* (cleaned up).) Here, Sections 124980 and 124977 do not conflict with one another, since it is possible for the Department to comply with both of them by consulting with the public before adopting an "emergency" regulation. Indeed, as Petitioners showed, in the recent past the Department did just that.[27] The Department therefore violated its mandatory obligations under Section 124980(a) when, without first consulting with the public, especially communities and groups particularly affected by programs on hereditary disorders, it adopted the emergency regulations, including the Exclusivity Regulation.

CONCLUSION AND ORDER

For the foregoing reasons, Petitioners' petitions for writ of mandate are granted. The Court will issue a writ of mandate and appropriate injunctive and declaratory relief precluding the Department from enforcing or implementing 17 Cal. Code Regs. § 6523(e). Petitioners shall submit a proposed writ of mandate and a separate proposed judgment.

IT IS SO ORDERED.

Dated: April 28, 2023

Ethan P. Schulman
Judge of the Superior Court

[27] In December 2019, the Department published a Notice of Emergency Rulemaking announcing it intended to adopt a regulation under the Hereditary Disorders Act, and it subsequently published a Notice of Proposed Rulemaking, scheduled a public hearing with a 45-day public comment period, and published a Final Statement of Reasons. The resulting regulations became effective on January 2, 2020. (Labcorp Pet. ¶ 31 & Exs. G, H.)

CERTIFICATE OF ELECTRONIC SERVICE
(CCP 1010.6(6) & CRC 2.260(g))

I, Felicia Green, a Deputy Clerk of the Superior Court of the County of San Francisco, certify that I am not a party to the within action.

On April 28, 2023, I electronically served ORDER GRANTING PETITIONERS' PETITIONS FOR WRIT OF MANDATE via File & ServeXpress on the recipients designated on the Transaction Receipt located on the File & ServeXpress website.

Dated: APR 28 2023

Mark Culkins, Interim Chief Executive Officer

By: Felicia Green
Felicia Green, Deputy Clerk